

Reprocessing and Reuse of Single Use Devices



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Outline



- The public perception of reuse of single use devices and the impetus for regulation
- The economics of reuse
- The players
- FDA's plan of action
- International impact

Perception and Impetus



- “Just the thought of this makes me queasy” says John Doe.
- This affects everyone
- Clear, opposing opinions
- Am I at risk?
- What is the government doing to protect me?

Economics



- Intended to skim some expenses
- Does it really save money?
 - Costs
 - | regulatory
 - | liability
 - | technical
 - | ethical
 - |etc

Players



- Hospitals (and others later?)
- OEMs
- Third parties (reprocessors and others)
- FDA
- JCAHO
- States
- others

FDA Plan



- You are a manufacturer
- You must comply with all requirements of F, D, and C Act
- Quality systems needed
- Hospital registration and other items
- Roll in of premarket requirements
- Future possibilities

International Impact



- Wait and see; or
 - You are a manufacturer; or
 - Don't do it!
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- Need for international consensus standards development